

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA**

JOHN ALBERICI, Individually and On  
Behalf of All Others Similarly Situated,

Plaintiff,

v.

RECRO PHARMA, INC., GERALDINE A.  
HENWOOD, STEWART MCCALLUM  
AND JOHN HARLOW,

Defendants.

Case No. 2:18-cv-02279-MMB

**SECOND AMENDED CLASS ACTION  
COMPLAINT FOR VIOLATION OF THE  
FEDERAL SECURITIES LAWS**

Hon. Michael M. Baylson

JURY TRIAL DEMANDED

Lead Plaintiff, the Recro Investor Group (defined herein) (“Plaintiff”), individually and on behalf of all other persons similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s second amended complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of Defendants’ public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Recro Pharma, Inc. (“Recro” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

### **NATURE OF THE ACTION**

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Recro securities between July 17, 2017 through May 23, 2018, both dates inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officers/executives.

2. Recro is a specialty pharmaceutical company that develops non-opioid therapeutics for the treatment of pain in the post-operative setting. Founded in 2007, Recro is headquartered in Malvern, Pennsylvania, and its securities trade on the NASDAQ Capital Market (“NASDAQ”) under the ticker symbol “REPH.”

3. The Company’s lead product is a proprietary injectable form of meloxicam (“IV meloxicam”), a long-acting preferential COX-2 inhibitor to be used for the management of moderate to severe pain.

4. Recro announced that it filed a New Drug Application (“NDA”) with the U.S. Food and Drug Administration (“FDA”) for IV meloxicam in July 2017, and the market buzzed with excitement with the hope that IV meloxicam would offer surgeons and their patients a long-lasting, once daily, non-opioid alternative drug to manage pain following surgery.

5. Before and after the filing of the NDA, Defendants misled investors about the market for IV meloxicam. Specifically, Defendants made numerous materially false and misleading statements that soft tissue surgeons – such as gastrointestinal/colorectal surgeons, and their patients – were “IV meloxicam target opportunities” even though Defendants *knew*, but

failed to disclose, that a significant majority of key opinion leader physicians communicating with Defendants specifically told them that they did **not** intend to use the drug in soft tissue procedures because the trial data for the drug's efficacy in soft tissue procedures was not compelling.

6. Defendants also misled investors to believe that, even though IV meloxicam was manufactured overseas, there was “oversight by our internal managers” (emphasis added). In reality, however, Recro did not have a handle on the manufacturing process. Specifically, the Company had only **one** employee – the Chief Executive Officer's brother, who had to commute from the U.S. to Ireland – to oversee the manufacturing of IV meloxicam and its packaging in Ireland. Although key opinion leader physicians voiced serious concerns to the Company about the inherent risks and specific lack of oversight of the Company's process for manufacturing IV meloxicam overseas, the Individual Defendants (defined herein) disregarded that expert feedback and conditioned investors to believe that the manufacturing process and oversight was copacetic.

7. On May 24, 2018, Recro shocked investors when it announced that the FDA had declined to approve Recro's NDA for IV meloxicam. In its Complete Response Letter (“CRL”) to the Company, the FDA stated that it was unable to approve the application in its current form “because data from ad hoc analyses and selective secondary endpoints suggest that ***the analgesic effect does not meet the expectations of the FDA.***” Additionally, the CRL raised ***chemistry, manufacturing and control-related “questions on extractable and leachable data*** provided in the NDA.” (Emphasis added.)

8. On this news, Recro's share price fell \$6.79, or 54.67%, to close at \$5.63 on May 24, 2018.

9. As a result of Defendants' materially false and misleading statements and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

### **JURISDICTION AND VENUE**

10. The claims asserted herein arise under and pursuant to §§ 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and § 27 of the Exchange Act.

12. Venue is proper in this Judicial District pursuant to § 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b) as Recro's principal executive offices are located within this Judicial District.

13. In connection with the acts, conduct and other wrongs alleged in this Second Amended Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

### **I. PARTIES**

14. Court-appointed Lead Plaintiff, Recro Investor Group, is comprised of investors Daniel Wessler, Charles Clark, Ronald Davidson and John Alberici. Plaintiff acquired Recro's securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

15. Defendant Recro is incorporated in Pennsylvania, and maintains its principal executive offices at 490 Lapp Road, Malvern, Pennsylvania 19355. Recro's securities trade on the NASDAQ under the ticker symbol "REPH."

16. Defendant Geraldine A. Henwood ("Henwood") founded Recro in 2007 and has served as the Company's Chief Executive Officer ("CEO"), President and Director since 2008. Henwood has served as a member of the Company's Management Team and Leadership Team at all relevant times.

17. Defendant Stewart McCallum ("McCallum") has served as the Company's Chief Medical Officer since December 2015. McCallum has served as a member of the Company's Management Team and Leadership Team at all relevant times.

18. Defendant John Harlow ("Harlow") has served as the Company Executive Vice President, Commercial since February 2018, and prior to that, served as Vice President, Marketing since October 2016. Harlow has served as a member of the Company's Leadership Team at all relevant times and Management Team since February 2018.

19. The Defendants referenced above in ¶¶ 16-18 are sometimes referred to herein as the "Individual Defendants."

20. The Individual Defendants possessed the power and authority to control the contents of Recro's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of the Company's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been

disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

## **II. SUBSTANTIVE ALLEGATIONS**

### **A. Background**

21. Recro is a specialty pharmaceutical company. During the Class Period, the Company operated through two distinct business divisions that were reported as separate segments – (i) an Acute Care division and (ii) a Contract Development and Manufacturing Organization (“CDMO”), located in Gainesville, Georgia.

22. The Company’s Acute Care division is primarily focused on developing products for hospital and other acute care settings. The Acute Care division’s lead product is IV meloxicam, a proprietary injectable form of meloxicam, a long-acting, non-opioid drug for the management of moderate-to-severe, acute postoperative pain. Meloxicam is a preferential COX-2 inhibitor, a subclass of non-steroidal anti-inflammatory drugs.

23. Recro purchased the rights to a patent-protected NanoCrystal® formulation of IV meloxicam and the CDMO facility from Alkermes Plc (“Alkermes”) on April 13, 2015.

24. In 2000, an oral meloxicam tablet (Mobic®) was approved by the FDA for signs and symptoms of osteoarthritis and rheumatoid arthritis, but it has a slow onset of action, largely due to poor water solubility, and is not currently approved for the treatment of acute pain. Recro claims that its proprietary IV form of the drug provides a faster onset of action of meloxicam and a rapid and sustained treatment for acute pain *via* IV routes.

25. Currently, opioids dominate the IV acute pain market. Recro touts IV meloxicam as having the potential to overcome many of the significant complications and side effects

associated with commonly-prescribed opioid drugs, including addiction, respiratory depression, constipation, excessive nausea and vomiting.

26. Recro is not an earnings-driven company. Indeed, during the Class Period, the Acute Care segment did not earn any revenue and Recro relied upon cash flows from its CDMO facility to offset the cost of developing IV meloxicam.

27. As IV meloxicam was the Company's lead product candidate in the Acute Care segment during the Class Period, the importance of securing NDA approval for IV meloxicam could not be overstated.

**B. It's a Family Affair – Nepotism Is Rampant at the Company**

28. Nepotism is rampant at the Company. Numerous examples illustrate how Henwood (the CEO, President and Director of the Company) uses Recro as an employment vehicle for her family members.

29. For example, Henwood's brother, Chris Sharr ("Sharr"), has served as the Company's Vice President, Manufacturing and Alliance Management since January 1, 2017. Sharr received a salary of \$243,000 in 2017 and was awarded options to purchase 43,600 shares of Recro common stock upon hire with a grant date fair value of \$229,772. Sharr has served as a member of the Leadership Team at all relevant times.

30. Henwood's sister, Diane Myers ("Myers"), has served as Recro's Senior Vice President, Regulatory Affairs and Quality Assurance since 2014. Myers earned \$762,028 in total compensation in 2017. Myers has served as a member of the Management Team and Leadership Team at all relevant times.

31. Henwood's sister-in-law, Suzanne Sharr (Sharr's wife), has served as Recro's Senior Director of Human Resources since January 1, 2017. Suzanne Sharr received a salary of

\$202,000 in 2017 and was awarded options to purchase 15,000 shares of Recro common stock upon hire with a grant date fair value of \$79,050.

**C. The Company Relies on Key Opinion Leader Physicians**

32. Key Opinion Leaders (“KOLs”) are well-respected, expert physicians in their field who provide thought leadership to their peers and the general public. They conduct research, write articles, and/or speak on behalf of pharmaceutical and life-sciences companies. As physicians attempt to choose from a myriad of drug options for patients, they often turn to KOLs for their knowledge and advice on specific drugs and options. As a result of their years of industry experience and medical affiliations, KOLs possess a unique credibility and have become entwined with the marketing of pharmaceuticals to lend credibility to claims of efficacy and safety.

33. Recro has a robust list of between 200 to 300 KOL physicians for IV meloxicam, including orthopedic surgeons, general surgeons, gastrointestinal/colorectal surgeons, anesthesiologists, and other physicians.

34. Recro relied on these KOLs to lend credibility to the Company’s claims about IV meloxicam’s efficacy and safety. Recro also relied upon the KOLs to provide feedback to the Company on IV meloxicam. Prior to and during the Class Period, the KOLs provided substantial feedback to Recro about a myriad of issues regarding IV meloxicam, as detailed below. Similarly, on March 22, 2019 – after the Class Period – the Company announced the receipt of a second IV meloxicam CRL from the FDA in a press release. During a conference call held later that day, Defendant Henwood stated (emphasis added): “The FDA did focus on the . . . fact that some patients have a reduction in pain relief in the waning hours of the dosing period. We believe that the product does perform well, that it has a role, that it could be useful in multi-



model analgesia. *That's based on KOL feedback . . .*” In other words, Defendants’ beliefs are informed by, *and purportedly based on*, KOL feedback.

**D. Confidential Witness No. 1 and Leadership Team Meetings**

35. KOLs for IV meloxicam frequently communicated with Confidential Witness No. 1 (“CW1”) and CW1’s Medical Affairs Team. CW1 was employed at the Company as its Regional Medical Affairs Director from June 2017 (prior to the Class Period) through September 2017, and as the National Director of Medical Affairs from October 2017 through May 2018.

36. CW1 was a member of Recro’s Leadership Team. CW1 led and coordinated medical conferences attended by KOLs, the majority of which he personally attended. At times, members of the Medical Affairs Team also accompanied him to the conferences, depending on the location of the conference. During such conferences, CW1 frequently spoke with Recro’s KOLs. CW1 also travelled to KOL facilities where he personally spoke with Recro’s KOLs. The Medical Affairs Team and CW1 documented their interactions with KOLs and always reported these interactions to Recro’s leadership, as described below.

37. CW1 reported to Defendant McCallum, the Company’s Chief Medical Officer.

38. Throughout the course of his employment, CW1 also participated in Recro’s weekly Leadership Team meetings, which were held every Monday in a conference room at the Company’s headquarters in Malvern, Pennsylvania. Leadership Team meetings were core team meetings during which updates and directions for IV meloxicam were discussed. Leadership from Recro’s Clinical, Medical Affairs, Business Development and Commerce departments attended the meetings.

39. CW1 often flew into Pennsylvania on Monday mornings to attend the Leadership Team meetings in person, but also attended the weekly meetings by telephone at times.

Regardless of the participation method, *CW1 confirmed that he attended all Leadership Team meetings during the course of his employment at Recro.*

40. The Leadership Team meetings were also consistently attended by the following Leadership Team members: (i) Defendant McCallum (Chief Medical Officer); (ii) Defendant Harlow (Executive Vice President, Commercial); (iii) Myers (Henwood's sister and Recro's Senior Vice President, Regulatory Affairs and Quality Assurance); (iv) Sharr (Henwood's brother, and Recro's Vice President, Manufacturing and Alliance Management); (v) Jim Witt (Director of Commercial Insights and Training); (vi) Cynthia Sherman (Vice President of Market Access); (vii) Fred Graff (Chief Commercial Officer); (viii) Greg Gangemi (Vice President of Sales); (ix) Janeese Carter (Director of Marketing), (x) Paul Baddeley (Director of Sales Operations and Analytics); and (xi) Libby Black (a consultant, who was hired as Recro's Senior Director of Global Health Outcomes in April 2018). Randy Mack ("Mack"), Recro's Senior Vice President, Development, and a member of the Leadership Team, attended the meetings to the extent the meeting focused on clinical development. Henwood, also a member of the Leadership Team, did not frequently attend Leadership Team meetings, but always received reports of these meetings from Defendants McCallum and Harlow, both of whom regularly interfaced with Henwood.

41. Over the course of CW1's employment, *at least 20 KOLs* told CW1 that he or she had concerns about nepotism at the Company with respect to Henwood's family, and questioned whether Henwood's family members, including Sharr, were qualified for their respective positions at the Company. In fact, CW1 stated that all eight members of the Medical Affairs Team, including CW1, had these concerns, as well as several members of the Marketing team.

42. These concerns were reported to the Individual Defendants. CW1 stated that, at weekly Leadership Team meetings, he and his Medical Affairs Team *reported* to the Company's leaders that the KOLs had concerns about: (i) nepotism; (ii) qualifications of Henwood's family members, including Sharr and his oversight of manufacturing in Ireland (discussed herein); (iii) the lack of safety data on bleeding risks for IV meloxicam; and (iv) the fact that KOLs were not intending to use IV meloxicam in their soft tissue procedures because the drug's efficacy clinical trial data was not compelling (discussed herein).

**E. The Company Filed a New Drug Application with the FDA**

43. Recro conducted efficacy and safety clinical trials for purposes of filing an NDA for IV meloxicam with the FDA.

44. In addition to conducting Phase 2 studies in acute pain models, the Company conducted randomized, double-blind, placebo-controlled Phase 3 acute post-operative pain studies, including a Phase 3 efficacy clinical trial in bunionectomy (hard tissue), a Phase 3 efficacy clinical trial in abdominoplasty (soft tissue), and a Phase 3 safety study.

45. Although Recro disclosed that the primary endpoints were met in both the bunionectomy and abdominoplasty clinical trials, the efficacy data for the abdominoplasty (soft tissue) clinical trial was far less robust than the data for the bunionectomy (hard tissue) clinical trial according to KOLs (and as further explained herein).

46. The financial well-being of the Company (and its stock price) depended on the FDA approving the drug, and the medical professionals embracing and using the drug. For investors, the operative question was not what IV meloxicam clinical trial data showed to lay people, *but how the clinical data was interpreted by medical experts*, for IV meloxicam's ultimate commercial success was wholly dependent on it being accepted by the various medical

communities. Thus, regardless of what the clinical data showed to lay people, because the majority of the Company's KOLs told Defendants that they did not intend to use the drug for soft tissue procedures, the drug's marketability was significantly lower than what was touted by the Company to investors.

47. Recro announced that it filed its NDA for IV meloxicam 30 mg on July 31, 2017 for the management of moderate to severe, acute postoperative pain.

48. On September 28, 2017, the Company issued a press release announcing that the FDA had accepted its NDA for IV meloxicam 30 mg for review.

49. On October 5, 2017, Recro announced that the FDA had set a "PDUFA" date of May 26, 2018 for its decision on the NDA. For reference, the Prescription Drug User Fee Act of 1992 ("PDUFA") typically calls for a period of 10 months to review such applications. PDUFA dates are deadlines by which the FDA must review NDAs.

50. Many drug companies voluntarily choose to disclose a PDUFA date to investors with the hope that doing so will lead to an increase in the company's stock price. Oftentimes, not only will a company's share price increase in anticipation of the FDA approving an NDA, but if the FDA ultimately grants approval of a company's NDA on a breakthrough drug, the company's share price will further increase as a result of such approval.

**F. The Company Receives a Complete Response Letter from the FDA Rejecting Recro's NDA for IV Meloxicam**

51. In a May 24, 2018 CRL, the FDA rejected Recro's NDA for IV meloxicam 30 mg.

52. CRLs inform drug companies that the review cycle for an NDA has been completed and that the NDA is *not* approvable. They lay out deficiencies and outline possible remedies. CRLs can have a devastating effect on a small company's share value. CRLs are

usually confidential. The FDA does not release CRLs publicly prior to approval because of confidentiality concerns.

53. According to Recro's May 24, 2018 press release, the CRL stated that the FDA was unable to approve the application in its submitted form for two reasons – (i) “because data from ad hoc analyses and selective secondary endpoints suggest that the analgesic effect does not meet the expectations of the FDA” and (ii) because the CRL raised chemistry, manufacturing and control or “CMC”-related “questions on extractable and leachable data provided in the NDA.”

54. During a May 24, 2018 morning conference call, Henwood deflected and stated that “[t]o the best of our understanding right now, there is a lack of clarity in the reviewer's mind about some of the data.”

55. Recro's share price was decimated as a result of the news that the FDA had rejected the application, falling over 50% in value. Specifically, in response to the news, the Company's stock price dropped \$6.79, or 54.67%, to close at \$5.63 on May 24, 2018.

**G. KOLs Voiced Concerns to the Company about the Quality and Oversight of Manufacturing IV Meloxicam Overseas**

56. The Company has entered into various agreements for the manufacturing and packaging of IV meloxicam.

57. For background, the Company (through its subsidiary – Recro Ireland Limited) is party to a July 10, 2015 Development, Manufacturing and Supply Agreement (“Supply Agreement”) with Alkermes (through a subsidiary – Alkermes Pharma Ireland Limited), for the clinical and, if approved by the FDA, commercial supply of injectable meloxicam. Pursuant to the Supply Agreement, Recro agreed to purchase its clinical supplies, and its commercial supplies, of bulk injectable meloxicam formulation exclusively from Alkermes, subject to certain

exceptions, for a period of time; and Alkermes provided development services with respect to the Chemistry, Manufacturing and Controls section of the NDA for injectable meloxicam.

58. On July 14, 2017, Recro announced that the Company, through its subsidiary Recro Ireland Limited, entered into a Master Manufacturing Agreement and Product Agreement with Patheon UK Limited to perform various manufacturing services, including providing sterile fill and finish services of bulk injectable meloxicam.

59. CW1 stated that *approximately 30%* of KOLs expressed their concern to CW1 about IV meloxicam being manufactured overseas. The KOLs were aware of and concerned about how “any blip on the radar” that the FDA found in the manufacturing and packaging process could sink approval of the drug. When CW1 spoke to KOLs about FDA approval “the thing that kept coming back up over and over again . . . the thing they were concerned about was a potential packaging issue or manufacturing issue because the manufacturer was in Ireland.” CW1 further reported that “this was one of the things the KOLs were concerned about that would keep this product from being approved.” “It came up in conversations with surgeons many times – ‘Let’s hope there are no[ ] manufacturing problems.’”

60. CW1 stated that the doctors’ concerns were based on their experience with the foreign manufacturing of drugs. The KOLs expressed concern that a manufacturing plant in Ireland may not have the same standards as the U.S., which could cause the plant to fail FDA pre-approval plant inspections. As such, oversight of the manufacturing and packing process was all the more important.

61. CW1 also stated that the KOLs had concerns about Recro’s level and quality of oversight of the manufacturing process of IV meloxicam. Simply put, the department was not adequately staffed. Recro had just *one* employee, Sharr, handling the oversight for

manufacturing IV meloxicam and its packaging in Ireland. But Sharr was based in Pennsylvania, and went back and forth from Pennsylvania to Ireland, spending only some of his time in Ireland actually overseeing the manufacturing and packaging process of IV meloxicam. To be adequately staffed, the department needed (at least) one full-time person on the ground in Ireland to oversee manufacturing, and one full-time person at the Company's Pennsylvania headquarters to handle in-house needs. Sharr was not able to handle these responsibilities by himself, in a part-time "on location" capacity.

62. Moreover, as noted above, Sharr is Henwood's brother and the KOLs who were aware of that relationship raised additional questions and concerns about how Sharr was not sufficiently qualified to oversee manufacturing. CW1 stated that "those were legitimate concerns" "and wham-o, one of the reasons it didn't get approved was this manufacturing defect . . . with the product leaching through the vial."

63. CW1 also stated that Sharr never struck CW1 as having a handle on manufacturing (a critical skill for an individual whose job title at Recro was Vice President, Manufacturing and Alliance Management). For example, in early 2018, a minor issue arose regarding the package label and insert for IV meloxicam, which fell within Sharr's area of responsibility. Even with this relatively small problem, CW1 stated that Sharr's management of the issue "was chaotic."

64. CW1 and CW1's Medical Affairs Team reported all of the KOLs' concerns about Sharr and foreign manufacturing of IV meloxicam to Recro's top leadership, including the Individual Defendants. As confirmed by CW1: "That was reported to the Company, they knew." "We reported all [of] that in our reports to corporate. We had conversations with the Leadership Team about what physicians were saying." CW1 confirmed that these concerns were reported to

Henwood, McCallum, Harlow and Mack in Leadership Team meetings and through written reports submitted to the Company throughout the course of his employment.

65. However, this information was not disclosed to the Company's investors. Accordingly, investors had no idea of the KOLs' concerns about overseas manufacturing shortcomings, or that Sharr did not have a handle on the manufacturing process for IV meloxicam and was in way deep over his head.

**H. Defendants Told Investors That Soft Tissue Surgeons and Their Patients Were "IV Meloxicam Target Opportunities" Even Though They Knew That a Significant Majority of KOLs Did Not Intend to Use the Drug in Soft Tissue Procedures**

66. As stated above, CW1 – who frequently communicated with KOLs, documented his and his team's interactions with KOLs, and reported these interactions to Company leadership – stated that Defendants knew that while 99.9% of KOLs were convinced that IV meloxicam should be used in orthopedic (or hard tissue) procedures, Defendants also *knew* that a *significant majority* of the Company's KOLs did *not* intend to use IV meloxicam in soft tissue procedures because the clinical trial data for the efficacy of IV meloxicam in hard tissue procedures (such as in the Phase III study in patients undergoing bunionectomy) was far more compelling than the clinical trial data for the drug's efficacy in soft tissue procedures (such as in the Phase III study in patients undergoing abdominoplasty procedures). In clinical trials, IV meloxicam showed a much less significant reduction in pain (or analgesic effect) in soft tissue procedures than in orthopedic procedures. Simply put, soft tissue clinical data for IV meloxicam was not as robust.

67. For perspective, soft tissue procedures are usually less painful for patients than hard tissue procedures, so the "range of pain" reduction that IV meloxicam may provide in soft tissue procedures is less dramatic. For example, on a pain scale of 0 to 10 (where 10 is the worst



pain imaginable), orthopedic (or hard tissue) surgery patients may rate their pain at an 8 after a procedure and before receiving painkillers. For soft tissue procedures, however, the rating may be closer to a 5. Thus, if physicians provide IV meloxicam to patients and reduce the pain in both types of procedures to a 3, the range of pain reduction for hard tissue procedures from 8 to 3 (a reduction of 5) is significantly more impressive than a range of pain reduction for soft tissue procedures from 5 to 3 (a reduction of 2).

68. Additionally, IV meloxicam's Phase III abdominoplasty trial missed 8 of 18 secondary endpoints, including the secondary endpoint of Patient Global Assessment of pain control as measured at hour 24. Thus, the potential exists for patients to have insufficient analgesic coverage (or breakthrough pain) toward the end of the 24-hour interval between doses.

69. CW1 estimated that *approximately 75%* of soft-tissue KOLs who had the ability to drive protocols in medical institutions *directly* told Recro representatives (including himself and his team) that they did not intend to use IV meloxicam in their procedures because of the trial data. As detailed below, this information was then reported by CW1 and his team to the Individual Defendants.

70. CW1 stated that he and his Medical Affairs Team went into the field to develop relationships with doctors, and particularly with KOLs who might be interested in using and promoting IV meloxicam. CW1 detailed how "we were working with KOLs at the major academic institutions across the country" "to develop protocols for the use of IV meloxicam post-surgery for pain." However, the KOLs were unwilling to include IV meloxicam in protocols for soft tissue procedures because it was not shown to be as effective as in hard tissue procedures.

71. Throughout CW1's employment, CW1 and his Medical Affairs Team reported to McCallum and Harlow and other leaders in multiple weekly Leadership Meetings that a significant majority of KOLs were resistant to using IV meloxicam for soft tissue procedures. With regard to how often these warnings were conveyed, CW1 stated: "It was definitely frequent."

72. Each week at Leadership Team meetings, which, as stated above, occurred every Monday at the Company's headquarters, CW1 and/or his team reported what they were hearing from KOLs which frequently included KOLs' opinions that the trial data was not compelling enough for them to use the drug in soft tissue procedures. KOL reluctance was especially strong among colorectal surgeon KOLs, who were also concerned about bleeding risks.

73. CW1 stated that he *personally reported* this information to McCallum and Harlow, as did his Medical Affairs Team. CW1 also stated that the copious amounts of feedback from KOLs about their resistance to using the drug in soft tissue procedures was *frequently reported to and discussed by* McCallum and Harlow, and that the information was provided to Henwood for additional discussions.

74. This information was also included in written reports submitted digitally to the Company regarding the Medical Affairs Team's interactions with each physician. In practice, CW1 submitted a compilation of the reports to Defendant McCallum, and McCallum then prepared a report about the KOL's feedback for Henwood.

75. CW1 stated that McCallum had *monthly* meetings with Henwood at the Company's Malvern headquarters to update her about information he was receiving from KOLs in the field. Harlow and Mack also participated in the monthly meetings with Henwood and McCallum. McCallum also submitted written reports to Henwood *each month* to coincide with

their meetings. CW1 helped McCallum prepare these reports by providing written content that was included in the reports to Henwood. In preparation for each meeting and the written report, CW1 provided McCallum with the feedback from KOLs that they did not intend to use IV meloxicam in soft tissue procedures. “There were reports that were done that I completed, that my team completed, that were sent directly to Stewart [McCallum] for his meetings with Gerri [Henwood].” “And Gerri would discuss all those things with the regulatory team that was preparing all of the FDA info. . . Those reports included that KOLs were reluctant to put IV meloxicam in their protocols.” CW1 *personally* saw that the written reports that McCallum submitted to Henwood included the information that KOLs did not want to use IV meloxicam for soft tissue procedures. “I definitely saw reports that contained that information.”

76. Recro also organized and hosted quarterly Advisory Board meetings in order to obtain additional expert opinion and feedback about IV meloxicam from KOLs in specific fields. CW1 reported that approximately 12 KOLs participated in each Advisory Board meeting. CW1 personally attended four Recro Advisory Board meetings in 2017 and 2018, which were run by McCallum. CW1 recalled that at least one of the Advisory Board meetings was held at the Grand Hyatt at the Dallas-Fort Worth International Airport. Two Advisory Boards were a combination of orthopedic and colorectal surgeons; one Advisory Board included only orthopedic surgeons; and one Advisory Board included only colorectal surgeons. CW1 stated that at the three Advisory Board meetings that included colorectal surgeons, the physicians made their opinions clear to McCallum and Harlow, who were present at the meetings, that the trial data did not convince the majority of them to start using IV meloxicam in their soft tissue procedures. CW1 confirmed that the physicians “clearly, absolutely voiced that the data for the soft-tissue procedure was not as compelling as the data for the orthopedic procedures.”

77. CW1 also recalled McCallum attending these Advisory Board meetings and going step-by-step through all the trial data with the KOLs, and that many of the colorectal surgeon KOLs told McCallum that they were not sold on IV meloxicam. CW1 stated that Harlow also attended the Advisory Board meetings and heard the same information from the colorectal surgeon KOLs. According to CW1, the KOLs told McCallum and Harlow that “this would be a very hard sell for them in their institutions to include on protocols for soft tissue procedures considering the data.”

78. During the Advisory Board meetings, the KOLs were also informed that Recro was pursuing a broad indication from the FDA for IV meloxicam for post-operative pain – both in hard and soft procedures. CW1 personally witnessed many of the KOLs on the Advisory Board question McCallum and Harlow as to why the Company was not seeking FDA approval for just the hard-tissue indication. CW1 stated that “[t]here were recommendations at those Advisory Board meetings that the Company focus their efforts on orthopedic rather than the larger post-surgical pain market.” Specifically, “the exact conversation that happened at those Advisory Board meetings was a flat-out statement from doctors – why are you pursuing an indication on post-surgery pain [that includes both hard and soft tissue procedures] . . . instead of going with [the] most compelling data in hard-tissue procedures? Why not go for the hard-tissue indication and get it on the market? They were looking at the data and asking why in the world would you submit an NDA for post-surgery pain [in general] when you have a drug that clearly has efficacy in orthopedic surgery.”

79. After Advisory Board meetings, CW1 helped McCallum prepare executive summaries of what occurred at the meetings. The executive summaries were then provided to Henwood. CW1 stated that the summaries of Advisory Board meetings with colorectal surgeons

reported that the majority of KOLs did not intend to use IV meloxicam in their procedures. He added: “They absolutely knew how the colorectal market felt.”

80. The Company also made the decision to focus its sales staff on orthopedic surgeons, and away from soft-tissue surgeons, which is indicative of where Recro believed that the true target market for IV meloxicam existed. CW1 stated that *this decision was based on feedback the Company received from KOLs*. CW1 recalled attending Launch Strategic meetings about training sales staff and discussing where sales representatives should focus their efforts. McCallum, Harlow and other executive leaders also participated in these meetings, and Henwood attended some of these meetings. CW1 stated: “We planned training for our sales people,” and “in the curriculum of training . . . we were definitely talking about focusing the team on the orthopedic procedures and staying away from recommending the product for soft tissue procedures. . . .”

81. Thus, even though Defendants *knew* that soft tissue surgeons were not a receptive market for IV meloxicam, they nevertheless made a series of false and misleading statements throughout the Class Period to convey to the market that soft tissue surgeons and their patients were “IV meloxicam target opportunities” for the Company. As investors subsequently learned, nothing could be further from the truth.

### **III. MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD**

#### **Statements Issued During the Third Quarter of 2017 (July 1, 2017-September 30, 2017)**

82. The Class Period begins on July 17, 2017, when the Company filed a Form 8-K with the SEC, signed by Henwood, along with a corporate investor presentation, attached as an exhibit, to be used by representatives of the Company “in various meetings with investors from

time to time.” The investor presentation stated the following, in relevant part, with respect to soft tissue procedures (emphasis added):

***IV Meloxicam Target Opportunity***

***Intra-abdominal Procedures***

- Surgeons have keen interest in:
  - Avoidance of opioids
  - Avoidance of troughs in existing non-opioid pain med options
- ***If approved, could answer needs through:***
  - Relief of moderate to severe pain over 24 hours***

Hospital Outpatient & Ambulatory Surgical Settings  
***Target Strategy – GI and Orthopedic Surgeons***

Hospital Outpatient Facilities

Top 426 facilities equal 50%

- ***4,100 facilities with targeted GI & Ortho (CPTs) procedures***

Ambulatory Surgical Centers

Top 300 centers equal 50%

- ***2,000 centers with targeted GI & Ortho procedures***

83. On August 17, 2017, the Company filed a Form 8-K with the SEC, signed by Henwood, along with an updated corporate investor presentation, attached as an exhibit, to be used by representatives of the Company “in various meetings with investors from time to time.” The investor presentation stated, in relevant part (emphasis added):

***IV Meloxicam Target Opportunity***

***Intra-abdominal Procedures***

- Surgeons have keen interest in:
  - Avoidance of opioids
  - Avoidance of troughs in existing non-opioid pain med options
- ***If approved, could answer needs through:***
  - Relief of moderate to severe pain over 24 hours***
  - Reducing LOS [length of stay]***

84. On September 19, 2017, the Company filed a Form 8-K with the SEC, signed by Henwood, along with an updated corporate investor presentation, attached as an exhibit, to be used by representatives of the Company “in various meetings with investors from time to time.” The investor presentation stated, in relevant part (emphasis added):

***IV Meloxicam Target Opportunity***

***Intra-abdominal Procedures***

- Surgeons have keen interest in:
  - Avoidance of opioids
  - Avoidance of troughs in existing non-opioid pain med options
- ***If approved, could answer needs through:***
  - Relief of moderate to severe pain over 24 hours***
  - Reducing LOS [length of stay]***

85. The statements referenced in ¶¶ 82-84 were materially false and/or misleading statements and/or failed to disclose that a significant majority of KOLs, on whom the Company relied, told Defendants that the clinical data for IV meloxicam’s efficacy in soft tissue procedures was not compelling and they did not intend to use the drug in soft tissue procedures. Indeed, the Company itself acknowledged the lack of interest in using the drug by planning the “curriculum of training” for its sales staff to focus on orthopedic procedures and to stay away from recommending the product for soft tissue procedures.

**Statements Issued During the Fourth Quarter of 2017 (October 1, 2017-December 31, 2017)**

86. On October 10, 2017, Recro issued a press release entitled “Recro Pharma Presents Phase III IV Meloxicam Clinical Efficacy Data in Patients Following Abdominoplasty at the 2017 American Society of Plastic Surgeons Annual Meeting.” The press release stated, in relevant part (emphasis added):

Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company focused on therapeutics for hospital and other acute care

settings, today announced an oral presentation highlighting clinical efficacy data from its Phase III study evaluating intravenous (IV) meloxicam 30mg for the treatment of acute postoperative pain in patients following abdominoplasty surgery. The poster was presented at Plastic Surgery The Meeting 2017, hosted by the American Society of Plastic Surgeons (ASPS), taking place October 6-10, 2017, in Orlando, FL. The poster, which was selected as a “Top 6” of the meeting, describes the clinical performance of IV meloxicam 30mg, including achievement of the study’s primary endpoint, a statistically significant difference in Summed Pain Intensity Difference (SPID) over the first 24 hours (SPID24) compared to placebo, along with detailed secondary endpoints.

“The Phase III results presented this year at Plastic Surgery The Meeting demonstrate the efficacy of IV meloxicam 30mg, including significant reductions in pain, as evidenced by SPID24, meaningful reductions in opioid rescue use and improvements across numerous other pain relief metrics,” said Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer of Recro Pharma and co-author of the poster. “On the safety front, IV meloxicam 30mg continues to demonstrate a favorable safety and tolerability profile with a low incidence of adverse events (AEs), serious AEs and infusion events. ***We believe these results demonstrate IV meloxicam 30mg’s ability to provide rapid and durable pain relief following abdominoplasty surgery and support its potential to be an attractive non-opioid alternative for physicians and patients for the treatment of acute, postoperative pain.***”

87. On October 11, 2017, the Company filed a Form 8-K with the SEC, signed by Henwood, along with an updated corporate investor presentation, attached as an exhibit, to be used by representatives of the Company “in various meetings with investors from time to time.” The investor presentation stated, in relevant part (emphasis added):

***IV Meloxicam Target Opportunity***

***Intra-abdominal Procedures***

- Surgeons have keen interest in:
  - Avoidance of opioids
  - Avoidance of troughs in existing non-opioid pain med options
- ***If approved, could answer needs through:***
  - Relief of moderate to severe pain over 24 hours***
  - Reducing LOS [length of stay]***

\*\*\*



***Targeted Accounts Cover ~12.6M Patients Across All Settings Of Care***

***Core Target Procedures***      Orthopedic (Hip/Knee, Spine other)  
General Surgery  
***GI/Colorectal***

88.      On November 14, 2017, the Company filed a Form 8-K with the SEC, signed by Henwood, along with updated information reflected in a slide presentation, attached as an exhibit, to present at the Jefferies 2017 London Healthcare Conference on November 15, 2017 and to be used by representatives of the Company “in various meetings with investors from time to time.” The presentation stated, in relevant part (emphasis added):

***IV Meloxicam Target Opportunity***

***Intra-abdominal Procedures***

- Surgeons have keen interest in:
  - Avoidance of opioids
  - Avoidance of troughs in existing non-opioid pain med options
- ***If approved, could answer needs through:***
  - Relief of moderate to severe pain over 24 hours***
  - Reducing LOS [length of stay]***

\*\*\*

***Targeted Accounts Cover ~12.6M Patients Across All Settings Of Care***

***Core Target Procedures***      Orthopedic (Hip/Knee, Spine other)  
General Surgery  
***GI/Colorectal***

89.      On November 28, 2017, the Company filed a Form 8-K with the SEC, signed by Henwood, along with updated information reflected in a slide presentation, attached as an exhibit, to be used by representatives of the Company “in various meetings with investors from time to time.” The presentation stated, in relevant part (emphasis added):

#### ***IV Meloxicam Target Opportunity***

##### ***Intra-abdominal Procedures***

- Surgeons have keen interest in:
  - Avoidance of opioids
  - Avoidance of troughs in existing non-opioid pain med options
- ***If approved, could answer needs through:***
  - Relief of moderate to severe pain over 24 hours***
  - Reducing LOS [length of stay]***

\*\*\*

##### ***Targeted Accounts Cover ~12.6M Patients Across All Settings Of Care***

***Core Target Procedures***      Orthopedic (Hip/Knee, Spine other)  
General Surgery  
***GI/Colorectal***

90. The statements referenced in ¶¶ 86-89 were materially false and/or misleading statements and/or failed to disclose that a significant majority of KOLs, on whom the Company relied, told Defendants that the clinical data for IV meloxicam's efficacy in soft tissue procedures was not compelling and they did not intend to use the drug in soft tissue procedures. Indeed, the Company itself acknowledged the lack of interest in using the drug by planning the "curriculum of training" for its sales staff to focus on orthopedic procedures and to stay away from recommending the product for soft tissue procedures.

##### **Statements Issued During the First Quarter of 2018 (January 1, 2018-March 31, 2018)**

91. On January 8, 2018, the Company filed a Form 8-K with the SEC, signed by Henwood, along with updated information reflected in a slide presentation, attached as an exhibit, to be used by representatives of the Company "in various meetings with investors from time to time." The presentation stated, in relevant part (emphasis added):

***IV Meloxicam Target Opportunity***

***Intra-abdominal Procedures***

- Surgeons have keen interest in:
  - Avoidance of opioids
  - Avoidance of troughs in existing non-opioid pain med options
- ***If approved, could answer needs through:***
  - Relief of moderate to severe pain over 24 hours***
  - Reducing LOS [length of stay]***

\*\*\*

***Targeted Accounts Cover ~12.6M Patients Across All Settings Of Care***

***Core Target Procedures***      Orthopedic (Hip/Knee, Spine other)  
General Surgery  
***GI/Colorectal***

92. On February 7, 2018, the Company filed a Form 8-K with the SEC, signed by Henwood, along with updated information reflected in a slide presentation, attached as an exhibit, to be used by representatives of the Company “in various meetings with investors from time to time.” The presentation stated, in relevant part (emphasis added):

***IV Meloxicam Target Opportunity***

***Intra-abdominal Procedures***

- Surgeons have keen interest in:
  - Avoidance of opioids
  - Avoidance of troughs in existing non-opioid pain med options
- ***If approved, could answer needs through:***
  - Relief of moderate to severe pain over 24 hours***
  - Reducing LOS [length of stay]***

\*\*\*

***Targeted Accounts Cover ~12.6M Patients Across All Settings Of Care***

***Core Target Procedures***      Orthopedic (Hip/Knee, Spine other)  
                                          General Surgery  
                                          ***GI/Colorectal***

93.      The presentation also stated that with respect to ***“Defining Our Market”***, there is a ***“Large Addressable Patient Opportunity” of “29 Million Patients” for “addressable procedures where [the] greatest IV meloxicam use is anticipated.”*** It is anticipated that ***“17%”*** of these 29 million patients will have ***“core procedures”*** by ***“gastrointestinal/colorectal surgeons”*** involving the ***“belly [and] bowel”***. (Emphasis added.)

94.      The presentation also has sections entitled “What We Have Learned: Market Research Feedback on Clinical Profile” and “IV Meloxicam Receptivity: Anticipated Usage”. The presentation stated (emphasis added): ***“In multiple market research surveys, the majority of HCP [health care professionals] surveyed said they would accept IV Meloxicam as a valuable addition upon approval to multimodal pain-management protocols. They estimated they would use the product in ~30% of their surgical cases.”*** The presentation also stated that ***“core target procedures”*** include ***“GI/Colorectal”***.

95.      On March 2, 2018, Recro filed its 2017 Annual Report on Form 10-K with the SEC, signed by Defendant Henwood, announcing the Company’s financial and operating results for the year ended December 31, 2017 (the “2017 10-K”). The 2017 10-K contained a certification pursuant to the Sarbanes-Oxley Act of 2002 signed by Defendant Henwood stating that the 2017 10-K ***“does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.”*** (Emphasis added.)

96. In the 2017 10-K, the Company stated in relevant part (emphasis added):

Manufacturing and Supply of our Acute Care Product Candidates

*We currently rely on contract manufacturers to produce drug product for our clinical studies under cGMPs [Current Good Manufacturing Practice regulations enforced by the FDA], with oversight by our internal managers.* We plan to continue to rely on contract manufacturers to manufacture development quantities of our product candidates, as well as commercial quantities of our product candidates, if and when approved for marketing by the FDA. We currently rely on a single manufacturer for the clinical supplies of our drug product for each of our product candidates and do not currently have agreements in place for redundant supply or a second source for any of our product candidates....

97. On March 9, 2018, the Company filed a Form 8-K with the SEC, signed by Henwood, along with updated information reflected in a slide presentation, attached as an exhibit, to be used by representatives of the Company “in various meetings with investors from time to time.” The presentation stated, in relevant part, that with respect to **“Defining Our Market”**, there is a **“Large Addressable Patient Opportunity”** of **“29 Million Patients”** for **“addressable procedures where [the] greatest IV meloxicam use is anticipated.”** It is anticipated that **“17%”** of these 29 million patients will have **“core procedures”** by **“gastrointestinal/colorectal surgeons”** involving the **“belly [and] bowel”**. The presentation also stated that **“core target procedures”** include **“GI/Colorectal”**. (Emphasis added.)

98. The presentation also stated the following, in relevant part, with respect to “IV Meloxicam Receptivity: Anticipated Usage” (emphasis added): **“In multiple market research surveys, the majority of HCP [health care professionals] surveyed said they would accept IV Meloxicam as a valuable addition upon approval to multimodal pain-management protocols. They estimated they would use the product in ~30% of their surgical cases.”**

99. The statements referenced in ¶¶ 91-98 were materially false and/or misleading statements and/or failed to disclose that (i) a significant majority of KOLs, on whom the

Company relied, told Defendants that the clinical data for IV meloxicam's efficacy in soft tissue procedures was not compelling and they did not intend to use the drug in soft tissue procedures. Indeed, the Company itself acknowledged the lack of interest in using the drug by planning the "curriculum of training" for its sales staff to focus on orthopedic procedures and to stay away from recommending the product for soft tissue procedures; and (ii) Recro did not have a handle on the manufacturing process for IV meloxicam, even though KOLs had raised concerns about Sharr's qualifications and his lack of oversight of manufacturing.

**Statements Issued During the Second Quarter of 2018 (April 1, 2018-June 30, 2018)**

100. On May 9, 2018, Recro filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended March 31, 2018. That same day, the Company's Management Team hosted an earnings call with analysts to discuss its first quarter 2018 results. During the earnings call, Defendant Harlow discussed Recro's lead product, IV meloxicam, stating in relevant part (emphasis added):

Given the increasing urgency of the national opioid crisis, we believe IV meloxicam has to potential to serve as a valuable analgesic alternative for healthcare institutions, physicians and patients.

*We believe, we've identified clear addressable segments of the market, that will benefit from IV meloxicam's profile. Segments in which we believe, IV meloxicam's profile provides both clinical and economic value.* From a clinical standpoint, we believe IV meloxicam can effectively treat pain, while reducing opioid consumption, which reduced opioid related adverse events.

From an economic standpoint, we believe IV meloxicam's durable 24-hour dosing profile will allow ambulatory surgical centers to perform more complex procedures with same date discharge, while managing pain. And hospitals to accelerate patients discharge and reduce length of stay through reduction of opioids.

*A pillar of our strategy is identifying the key surgeons specifically orthopedic surgeons, general surgeons and GI colorectal surgeons. The procedures conducted by these surgeons represent a primary opportunity both in ambulatory surgical centers and in hospitals.*

101. On May 10, 2018, the Company filed a Form 8-K with the SEC, signed by Henwood, along with updated information reflected in a slide presentation, attached as an exhibit, to be used by representatives of the Company “in various meetings with investors from time to time.” The presentation stated that with respect to ***“Defining Our Market”***, there is a ***“Large Addressable Patient Opportunity”*** of ***“29 Million Patients”*** for ***“addressable procedures where [the] greatest IV meloxicam use is anticipated.”*** It is anticipated that ***“17%”*** of these 29 million patients will have ***“core procedures”*** by ***“gastrointestinal/colorectal surgeons”*** involving the ***“belly [and] bowel”***. The presentation also stated that ***“core target procedures”*** include ***“GI/Colorectal”***. (Emphasis added.)

102. The presentation also stated the following, in relevant part, with respect to “IV Meloxicam Receptivity: Anticipated Usage” (emphasis added): ***“In multiple market research surveys, the majority of HCP [health care professionals] surveyed said they would accept IV Meloxicam as a valuable addition upon approval to multimodal pain-management protocols. They estimated they would use the product in ~30% of their surgical cases.”***

103. The statements referenced in ¶¶ 100-102 were materially false and/or misleading statements and/or failed to disclose that a significant majority of KOLs, on whom the Company relied, told Defendants that the clinical data for IV meloxicam’s efficacy in soft tissue procedures was not compelling and they did not intend to use the drug in soft tissue procedures. Indeed, the Company itself acknowledged the lack of interest in using the drug by planning the “curriculum of training” for its sales staff to focus on orthopedic procedures and to stay away from recommending the product for soft tissue procedures.

### **The Truth Emerges**

104. On May 24, 2018, Recro issued a press release entitled “Recro Pharma Receives Complete Response Letter from the FDA,” disclosing that the FDA had declined to approve Recro’s New Drug Application for IV meloxicam (the “May 24, 2018 Revelation”). The press release stated in relevant part (emphasis added):

Recro Pharma, Inc. (Nasdaq: REPH), a revenue generating specialty pharmaceutical company focused on therapeutics for the hospital and other acute care settings, today announced it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) Office of Drug Evaluation II regarding the New Drug Application (NDA) for IV meloxicam.

The CRL stated that although the outcome of the pivotal phase III trials demonstrated statistically significant outcomes on the primary endpoints, *the FDA is unable to approve the application in its current form. The CRL states that data from ad hoc analyses and selective secondary endpoints suggest that the analgesic effect does not meet the expectations of the FDA. In addition, the CRL raised CMC [or Chemistry, Manufacturing and Controls]-related questions on extractable and leachable data provided in the NDA.*

105. On this news, Recro’s share price fell \$6.79, or 54.67%, to close at \$5.63 on May 24, 2018.

106. The May 24, 2018 Revelation disclosed for the first time what Defendants had been told by KOLs during the Class Period – that the clinical data for IV meloxicam suggested that the drug did not have a sufficient analgesic effect. As detailed above, throughout the Class Period the KOLs had specifically (and repeatedly) told Defendants that the trial data for the drug’s efficacy in soft tissue procedures was not compelling, and that therefore a significant majority of KOLs did not intend to use the drug in soft tissue procedures, which *directly contradicts* many of Recro’s statements to investors about the market and target usage of IV meloxicam.

107. The May 24, 2018 Revelation also disclosed for the first time that Recro did not have a handle on the manufacturing process, even though KOLs had specifically raised concerns



during the Class Period about Sharr's qualifications and his oversight of manufacturing overseas, which Recro failed to disclose or remedy. The FDA saw small peaks in the drug formulation and raised concerns that the drug could extract/leach foreign particles from the vial's rubber stopper. This corrective disclosure directly contradicts Recro's prior statement that its internal managers had appropriate oversight of the overseas manufacturing process for IV meloxicam.

108. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

#### **IV. PLAINTIFF'S CLASS ACTION ALLEGATIONS**

109. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Recro securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

110. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Recro securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Recro or its transfer agent and may be notified of

the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

111. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

112. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

113. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business and operations of Recro;
- whether the prices of Recro securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

114. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

115. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Recro securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Recro securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

116. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

117. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

**COUNT I**

**(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder  
Against All Defendants)**

118. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

119. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

120. During the Class Period, Defendants engaged in a plan, scheme, and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Recro securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Recro securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

121. Pursuant to the above plan, scheme, and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to

influence the market for Recro securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Recro's business.

122. By virtue of their positions at Recro, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

123. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As senior officers/executives of Recro, the Individual Defendants had knowledge of the details of Recro's internal affairs.

124. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Recro. As officers/executives of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Recro's businesses, operations, and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Recro securities was

artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Recro's business which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Recro securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

125. During the Class Period, Recro securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Recro securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Recro securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Recro securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

126. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

127. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure of the truth to the investing public.

## **COUNT II**

### **(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)**

128. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

129. During the Class Period, the Individual Defendants participated in the operation and management of Recro, and conducted and participated, directly and indirectly, in the conduct of Recro's business affairs. Because of their senior positions, they knew about the adverse non-public information with respect to which Plaintiff and the other members of the Class complain.

130. As officers and/or executives of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Recro's business and operations, and to correct promptly any public statements issued by Recro which had become materially false or misleading.

131. Because of their positions of control and authority as senior officers/executives, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Recro disseminated in the marketplace during the Class Period concerning Recro's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Recro to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Recro within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Recro securities.

132. Each of the Individual Defendants, therefore, acted as a controlling person of Recro. By reason of their senior management positions of Recro, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Recro to

engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Recro and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

133. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Recro.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff demands judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;
- B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and
- D. Awarding such other and further relief as this Court may deem just and proper.

**DEMAND FOR TRIAL BY JURY**

Plaintiff hereby demands a trial by jury.

Dated: April 24, 2020

Respectfully submitted,

/s/ Brenda Szydlo  
By: Brenda Szydlo

**POMERANTZ LLP**

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Brenda Szydlo (admitted *pro hac vice*)  
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**CERTIFICATE OF SERVICE**

I hereby certify that on April 24, 2020, a copy of the foregoing was filed electronically. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's CM/ECF System.

/s/ D. Seamus Kaskela  
D. Seamus Kaskela